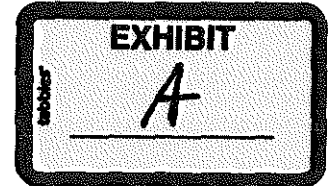


DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD



ORDER OF MEDICARE APPEALS COUNCIL
REMANDING CASE TO ADMINISTRATIVE LAW JUDGE
Docket Number: M-17-9374

In the case of

Claim for

C.L.
(Appellant)

Supplementary Medical
Insurance Benefits (Part B)

Carol Lewis
(Beneficiary)

XXX-XX-2438A
(HIC Number)

Noridian Healthcare Solutions
(Contractor)

1-5578134237
(ALJ Appeal Number)

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated August 4, 2017, because there is an error of law material to the outcome of the claims. See 42 C.F.R. § 405.1110. The ALJ's decision, issued solely on the basis of the written record, found Medicare coverage warranted for a disposable sensor and an external transmitter used with the appellant/beneficiary's continuous glucose monitor (CGM) provided on May 23, 2016, and May 27, 2016, respectively.

By memorandum dated September 26, 2017, the Centers for Medicare and Medicaid Services (CMS) asked the Council to review the decision on its own motion pursuant to 42 C.F.R. § 405.1110. We admit the CMS memorandum into the record as Exhibit (Exh.) MAC-1.

The appellant, through counsel, submitted exceptions to CMS' memorandum by facsimile dated October 17, 2017, which we admit into the record as Exh. MAC-2. The appellant also submitted two duplicate copies of the exceptions, one by mail and one by another facsimile, which we exclude from the record as duplicative, but they marked for identification purposes as Exh. MAC-3 (Excluded). The appellant also submitted additional

evidence in a letter dated November 2, 2017, to support her claims at issue in this case, as well as a claim pending before the Council under M-17-3263 concerning the appellant's request for review of ALJ Appeal No. 1-4852017030. Because the appellant's letter does not indicate that a copy was provided to CMS for the claims at issue in this case, we exclude this letter along with the attached evidence from the record in this case, but they are marked for identification purposes as Exh. MAC-4 (Excluded).¹ 42 C.F.R. § 405.1110(b)(2) (stating that a party submitting comments to the Council must send such comments to CMS and all other parties to the ALJ's action who received a copy of the ALJ's action).

The Council has carefully considered the record before the ALJ, CMS' memorandum, and the appellant's response. Based upon that review, the Council agrees with CMS that the ALJ's decision contains an error of law material to the outcome of the claims. Because the appellant was not offered the opportunity for a hearing and did not waive her right to a hearing, we hereby vacate the ALJ's decision and remand this case for further proceedings, including a hearing and a new decision. See 42 C.F.R. § 405.1110(d).

AUTHORITIES

Medicare is a defined benefits program. Section 1832(a) of the Social Security Act (Act) provides that benefits under Medicare Part B include "medical and other health services." Section 1861(s)(6) of the Act defines "medical and other health services" as including durable medical equipment (DME). Section 1861(n) of the Act lists certain items that are classified as DME. However, by its own terms, section 1861(n) is not an exhaustive list of those items that qualify as DME. Thus, the fact that an item is not listed in section 1861(n) does not necessarily mean that it is not DME.

The regulation at 42 C.F.R. § 414.202 defines DME as equipment that: can withstand repeated use; has an expected life of at least three years; is primarily and customarily used to serve a medical purpose; generally is not useful to an individual in the absence of an illness or injury; and is appropriate for use in

¹ The Council has added a copy of the appellant's November 2, 2017 correspondence to the claim file for M-17-3263, and will separately consider whether there are grounds to admit it into that record when the Council issues an action in that case.

the home. Medicare covers DME if it: (1) meets the definition of DME; (2) is medically "reasonable and necessary;" and (3) is used in the beneficiary's home. Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, Ch. 15, § 110.

CMS has issued national coverage determinations (NCDs) that specifically address certain items and services. "An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a). "NCDs generally outline the conditions for which an item or service is considered to be covered (or not covered) under § 1862(a)(1) of the Act or other applicable provisions of the Act." Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 13, § 13.1.1. NCDs are binding on all contractors, ALJs, and the Council. 42 C.F.R. § 405.1060(a)(4). CMS has issued NCD 280.1, which repeats the regulatory definition of DME found at 42 C.F.R. § 414.202 and NCD 40.2 (*Home Glucose Blood Monitors*).

A Medicare administrative contractor may issue a local coverage determination (LCD) that "is a decision . . . whether to cover a particular item or service on a [contractor]-wide, intermediary wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the [Act] (i.e., a determination as to whether the item or service is reasonable and necessary.)" MPIM, Ch. 13, § 13.1.3. Information that is not related to reasonableness and necessity coverage criteria, such as benefit category and statutory exclusions, is published through a Policy Article. *Id.* ALJs and the Council are not bound by LCDs and program guidance, "but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). If an ALJ or the Council declines to follow an LCD, the decision must explain the basis for not doing so. 42 C.F.R. § 405.1062(b). Pertinent here are LCD L33822 (*Glucose Monitors*) and its related Policy Article A52464 (*Glucose Monitor*).

BACKGROUND

At issue is the appellant's claims for Medicare coverage of the CGM disposable sensor (HCPCS code A9276) and external transmitter (HCPCS code A9277) provided to her on May 23, 2016, and May 27, 2016, respectively. See Exh. 1 at 25, 36-37.

A CGM system consists of three parts: a glucose sensor, a transmitter, and a receiver that displays real-time glucose

information. Individuals who face daily challenges in managing glycemic levels and trying to avoid hypoglycemic and hyperglycemic excursions benefit from the use of continuous glucose monitoring. However, maintaining direct access to the blood on a continuous basis for an extended period is not practical. Instead, a CGM glucose sensor can continuously measure glucose concentration in the *interstitial fluid*, which is a method for *estimating* blood glucose. The glucose concentration is then communicated to the transmitter, which fits onto the sensor and sends the data to a receiver. CGM sensors need to be replaced regularly, although the exact timeframe differs by brand. If the glucose levels are high or low, depending on the brand/model, a user can then confirm those levels with a finger stick and take appropriate action. Thus, while involving the same goals, a CGM is distinguishable from a blood glucose monitor, in that the latter measures *blood* glucose levels.

The record indicates that the appellant has Type 1 diabetes. See Exh. 4 at 3-4. The appellant experiences large fluctuations in her blood glucose levels and she is hypoglycemic unaware. See *id.* The appellant has been using a CGM for about 10 years, and her private insurer had covered her CGM before she enrolled in Medicare. See *id.*

At the lower levels of appeal, the Medicare contractor and Qualified Independent Contractor (QIC) denied coverage finding that Medicare guidelines state that CGMs are deemed precautionary and not covered under the DME benefit. See Exh. 1 at 1-4, 17-18. The appellant, through counsel, requested a hearing before an ALJ and did not waive her right to appear. See Exh. 2 at 1-2; Exh. 4 at 3.

Pursuant to 42 C.F.R. § 405.1038(a), the ALJ issued a decision, wholly favorable to the appellant, without conducting a hearing. Dec. at 1. The ALJ found that LCD L33822 and Policy Article A52464 provide that CGMs are considered precautionary and therefore non-covered under the DME benefit. *Id.* at 8-9. The ALJ however declined to follow the LCD and Policy Article, explaining that:

The Appellant has provided randomized studies published in peer-reviewed medical journals as well as practice guidelines from the Journal of Diabetes Science and Technology Guidance, New England Journal of Medicine, Annals of Internal Medicine, and American

Association of Clinical Endocrinologist all of which support the use of CGM to improve glycemic control in Type I diabetes. Thus, instead of being classified as precautionary in nature the medical community has found the CGM to be beneficial to monitor and treat diabetes.

Id. at 9.

The ALJ further explained that:

Guidance as to coverage for CGM devices is also found in CMS Ruling No. CMS-1682-R issued on January 12, 2017. It states therapeutic continuous blood glucose monitors which provide information that can be used to make diabetes treatment decisions meets all 5 DME criteria set forth under 42 CFR 414.202 and therefore, it is recognized as durable medical equipment under Section 1861(n) of the Act. While this ruling is not retroactively applicable, the undersigned finds that the analysis used to determine the CGM meets the criteria set forth . . . under 42 CFR 414.202 [are] applicable here. The CGM can withstand repeated use, has an expected lifetime of at least 3 years, is primarily and customarily used to serve a medical purpose, generally is not useful in the absence of injury or illness, and is appropriate for use in the home. Accordingly, the CGM falls within the Medicare DME benefit.

Dec. at 9.

Having found that the appellant's CGM falls within the Medicare DME benefit, the ALJ considered the appellant's condition and found that the CGM items furnished to the appellant are medically necessary and covered by Medicare. Specifically, the ALJ stated:

In the instant case the record reflects the Appellant's medical history is significant for insulin dependent brittle diabetes and hyperglycemic unawareness. Despite following a strict diet and exercise regime[n] she exp[e]rienced uncont[r]olled blood glucose swings resulting in hypoglycemic and hyperglycemic episodes. Here the CGS [sic] is not precautionary but instead used for making diabetic

treatment decisions. Given the Appellant's medical condition a CGM is medically necessary to monitor for life threatening episodes of hyperglycemia and hypoglycemia and allow for diabetic treatment. The undersigned finds that the CGS [sic] is covered and medically necessary. Therefore, the external transmitter . . . and disposable invasive sensor provided by [the supplier] are also covered and medically necessary. The [supplier] is entitled to reimbursement for the same.

Dec. at 9.

CMS' Referral Memorandum

CMS argues that the ALJ's decision contained an error of law material to the outcome of the claims, because the ALJ's analysis did not consider what constituted a precautionary item, or whether any law or policy that existed on the dates of service established or precluded Medicare coverage of CGMs and related items. First, CMS argues that the ALJ made an incorrect assumption that an item that is beneficial cannot also be precautionary in nature. On this point, CMS asserts that CMS and its contractors have published guidance concerning Medicare's perspective on precautionary items and CGM systems prior to the dates of service in this appeal. For example, CMS states that NCD 280.1 identifies some items that do not qualify as DME because they are deemed precautionary and not therapeutic in nature, such as portable oxygen systems. CMS also states that the MBPM, Ch. 15, §110.1(B), reiterates that precautionary-type equipment such as preset portable oxygen units are presumptively nonmedical in nature. Exh. MAC-1 at 2, 7-9.

Next, CMS cites to a Joint DME MAC Publication advisory article posted on August 13, 2014, which addressed coverage and correct coding of CGM devices, and stated:

Current CGM systems are FDA-approved only as a secondary source for glucose monitoring. According to the FDA labeled indications, all CGM device readings must be confirmed with a capillary blood glucose monitor and users are cautioned against making insulin dosage changes based solely on CGM system determinations. Consequently, CGM devices are considered precautionary equipment. The Medicare [DME] benefit excludes precautionary items from

coverage; therefore, claims for CGM systems are denied as statutorily non-covered, no benefit.

Medicare covers necessary supplies used with covered items. When the base item is non-covered, the related supplies are also not covered. Claims for supplies used with CGM systems are denied as statutorily non-covered, no benefit.

Coverage and Correct Coding of Continuous Glucose Monitoring Devices (https://www.dmeopdac.com/resources/articles/2014/08_13_14.html) (last visited Dec. 12, 2017); see also Exh. MAC-1 at 9.

Next, CMS asserts that in 2014 and again in 2015, identical bills were introduced in the U.S. Senate and the House of Representatives to amend Title XVIII of the Act to extend the Medicare Part B benefit to provide Medicare coverage of CGM devices furnished to CGM qualified individuals. However, CMS also notes that the bills have not been passed or enacted into law. Exh. MAC-1 at 9.

Next, CMS asserts that, although the ALJ addressed Ruling CMS-1682-R, the Ruling clarifies that a CGM used in conjunction with, instead of in place of, a blood glucose meter is precautionary in nature. CMS also asserts that prior to the January 12, 2017 effective date of the Ruling, Medicare regarded all CGMs as precautionary in nature. CMS further asserts that even if the extension of coverage to therapeutic CGMs had been applicable in this case, the record does not identify the particular CGM system the appellant was using on the dates of service at issue. Exh. MAC-1 at 10-11.

CMS ultimately concludes that "[n]o statute, regulation, CMS ruling, NCD, LCD, or other policy supports coverage for the sensors and transmitters at issue in this case" and that "the ALJ's award of coverage in this case amounts to an error of law." Exh. MAC-1 at 11.

The Appellant's Exceptions

The appellant first asserts that that the Secretary of the Dept. of Health and Human Services (Secretary) is barred by collateral estoppel from re-litigating the issue in this case. On this point, the appellant states that she has received favorable ALJ decisions on the same issue in other cases and that those

decisions had become final because the Secretary did not appeal those decisions. Exh. MAC-2 at 2-3.

Next, the appellant asserts that CMS challenges the irrelevant issue of whether a CGM is precautionary, but that issue was not the basis of the ALJ's decision. The appellant also asserts that, even if the Policy Article and LCD deemed CGMs precautionary, the ALJ declined to follow them based on the appellant's medical history and need. Next, the appellant asserts that CMS repeatedly refers to Policy Article A52464, but in the appellant's view, Policy Articles do not contain coverage policies and are not entitled to deference. Exh. MAC-2 at 3-5.

Next, the appellant asserts that a CGM is a blood glucose monitor within the meaning of the Act, NCD 280.1, and the LCD. On this point, the appellant states that "[a] CGM measures glucose in the interstitial fluid", and that "[g]lucose values in the interstitial fluid are correlated with glucose values in blood itself and are, therefore, an indirect measure of blood glucose." Exh. MAC-2 at 5-6.

Next, the appellant asserts that CMS' reliance on various Congressional bills is misguided because "[t]hose bills came long after the enactment of the statutes at issue, and as such, provide no guidance as to the meaning of the terms therein." Exh. MAC-2 at 6.

Next, the appellant asserts that, although CMS' referral indicates uncertainty over the type of CGM device that is at issue, the appellant was indeed using a Dexcom G5 CGM device during the dates of service at issue. The appellant also asserts:

As noted in [the ALJ's] decision, CMS Ruling 1682-R indicated that devices like the Dexcom G5 were non-precautionary and otherwise qualified as DME. However, the Ruling also indicated that it only applied to claims after January 12, 2017 which is later than the date of coverage at issue in this case. Thus, to the extent that denial is premised on CMS Ruling 1682-R only applying after January 2017, it must be contended that the exact same device that was non-precautionary, DME and covered on or after January 12, 2017, was precautionary, not DME and not covered on January 11, 2017 and before. That position is untenable.

Exh. MAC-2 at 6-7.

DISCUSSION

We have reviewed the record before the ALJ, as well as CMS' and the appellant's arguments to us, in the context of the applicable authorities. We find that CMS' request for the Council's own motion review of the claim at issue is not barred by collateral estoppel. We also agree with CMS that the ALJ erred as a matter of law because the ALJ misapplied the CMS Ruling and because the ALJ did not consider all the authorities and guidance applicable to the dates of service at issue. Because there is no evidence that this specific CGM system, on the dates of service, is included within the statutory DME benefit category, any equipment associated with it, such as the sensor and transmitter at issue here, also cannot be covered by Medicare. We discuss our rationale below.

CMS's appeal is not barred by collateral estoppel

The appellant argues that CMS, on behalf of the Secretary, is barred by collateral estoppel from re-litigating the issue in this case. Exh. MAC-2 at 2-3. However, collateral estoppel is an affirmative defense generally pleaded by defendants in civil actions and is not applicable in administrative appeals as in the case here. More importantly, under Medicare regulations, both ALJs and the Council conduct *de novo* hearings and are required to hold *de novo* considerations of the facts and laws. See 42 C.F.R. §§ 405.1000, 405.1100. Therefore, neither prior ALJ nor Council decisions are precedential and thus are not binding on any subsequent decision issued by an ALJ or the Council. Accordingly, we find that CMS' request for the Council's own motion review of the claims at issue is not barred by collateral estoppel.

The ALJ erred by misapplying CMS Ruling 1682-R

The Council finds the ALJ erred as a matter of law by misapplying CMS Ruling 1682-R. The CMS Ruling, which was issued after the dates of service at issue, states that therapeutic CGM systems will be considered DME if the CGM system is "approved by the FDA for use in place of a blood monitor for making diabetes treatment decisions[;]" generally is not useful to the individual in the absence of an illness or injury; is appropriate for use in the home; and includes a durable

component. CMS Ruling at 13-14 (emphasis added). However, the CMS Ruling also specifically states that "Medicare does not cover CGMs approved by the FDA as *adjunctive devices to complement, not replace*, information obtained from blood glucose monitors." *Id.* at 6-7 (emphasis added). The CMS Ruling further states that: "In our view, such devices are not used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, and therefore, have not been covered under Medicare because they are not considered to serve the medical purpose of making diabetes treatment decisions." *Id.*

Moreover, the CMS Ruling specifically states that it "does not apply to items and services furnished prior to the effective date of the Ruling." The CMS Ruling "was to be applied prospectively[] only." CMS Ruling at 1, 15. Thus, the Council finds that the CMS Ruling cannot be applied to dates of service prior to its effective date of January 12, 2017. ALJs are bound by CMS Rulings. See 42 C.F.R. § 423.1063(b). Therefore, the ALJ's interpretative analysis supporting the appellant's claims with dates of service May 23, 2016, and May 27, 2016, however well-intentioned, was *specifically precluded by law*. Rather, the ALJ's review was limited to application of the authorities in place on the dates of service at issue.

The ALJ did not consider the authorities and guidance applicable to the dates of service at issue

In this case, the ALJ explained his reason for declining to follow LCD L33822 and Policy Article A52464, which provide that CGMs are considered precautionary and therefore non-covered under the DME benefit. Dec. at 9. However, the ALJ erred as a matter of law because he did not consider the other authorities and guidance applicable to the dates of service at issue, which do not support coverage for the CGM device and related accessories at issue. Under 42 C.F.R. § 414.202, DME is equipment that, among other requirements, must be "primarily and customarily used to serve a medical purpose." As the MBPM makes clear, "This is true even though the item has some remote medically related use." MBPM, Ch. 15 § 110.1 (Rev. 161, Effective April 1, 2013). The appellant's CGM system, however, does not have a primary medical purpose because it is a precautionary item. While the term "precautionary" is not a statutorily defined term, it refers to the requirement that DME must itself serve a medical purpose. *Id.* Where a beneficiary must still use another device to accomplish the medical purpose

at issue, the device is essentially used as an additional precaution, but not for a primary medical purpose.

As CMS notes, NCD 280.1 identifies some items that do not qualify as DME because they are deemed precautionary and not therapeutic in nature. Exh. MAC-1 at 8-9. Additionally, the MBPM, Ch. 15, § 110.B, reiterates that precautionary-type equipment is presumptively nonmedical in nature. See *id.* Further, the Joint DME MAC Publication advisory article posted on August 13, 2014 referenced in CMS' referral memorandum and effective on the dates of service at issue clearly states that CGM devices are considered precautionary equipment. See *id.* The ALJ erred as matter of law because he did not consider and analyze these authorities and guidance pertaining to Medicare coverage of precautionary and CGM devices under the DME benefit.

The appellant asserts in her exception to the CMS' referral memorandum that the CGM device for the sensors and transmitters at issue is a Dexcom G5 and that the device falls under the statutory DME benefit pursuant to Ruling 1682-R. Exh. MAC-2 at 6-7. However, as discussed above, the CMS Ruling cannot be applied to the dates of service at issue. We note that, prior to December 20, 2016 and during the dates of service at issue, the FDA found that the Dexcom G5 was only "indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices." See FDA Premarket Approval Application (PMA) P120005/S041: Summary of Safety and Effectiveness Data, https://www.accessdata.fda.gov/cdrh_docs/pdf12/120005S041b.pdf (last visited Dec. 12, 2017).

Furthermore, there is no NCD or LCD that extends coverage to the CGM system in this case. NCD 40.2 and LCD L33822 authorize coverage of blood glucose monitors if, among other criteria, the patient has diabetes and a physician has concluded that the patient has had sufficient training using the blood glucose monitor. However, the NCD and LCD are inapplicable in this case because this CGM system does not constitute a blood glucose monitor. The appellant's particular CGM system measures glucose in the interstitial fluid and not in the blood. The appellant asserts that a CGM is a blood glucose monitor within the meaning of the Act, NCD 280.1, and the LCD, because "[g]lucose values in the interstitial fluid are correlated with glucose values in blood itself and are, therefore, an indirect measure of blood glucose." Exh. MAC-2 at 5-6. However, NCD 40.2 specifically defines blood glucose monitors as "meter devices that read color

changes produced on specially treated reagent strips by glucose concentrations in the patient's blood." Accordingly, despite the appellant's artful pleading, we find that CGMs do meet the definition of blood glucose monitors within the meaning of the Act, NCD 280.1, and the LCD.

In sum, we concur with CMS that the ALJ erred as matter of law because he did not consider and analyze all the authorities and guidance pertaining to Medicare coverage of CGM devices under the DME benefit. Because the appellant was not offered the opportunity for a hearing and did not waive her right to a hearing, we hereby vacate the ALJ's decision and remand this case for further proceedings, including a hearing and a new decision. See 42 C.F.R. § 405.1110(d).

INSTRUCTIONS ON REMAND

On remand, the ALJ will offer the parties an opportunity for a hearing. See 42 C.F.R. § 405.1020(c)(1). Any waiver of the right to a hearing shall be documented in writing. The ALJ will issue a new decision consistent with this discussion. In doing so, the ALJ should consider the arguments raised in CMS' referral memorandum and the appellant's exceptions to that memorandum. If the ALJ concludes that Medicare does not cover the CGM system, then the ALJ should analyze the issue of financial responsibility for the non-covered items.

The ALJ may take further action not inconsistent with this order.

MEDICARE APPEALS COUNCIL



Gilde Morrisson

Administrative Appeals Judge



Deborah S. Samenow

Administrative Appeals Judge

Date: DEC 19 2017